K103688
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

JAN 14 2011

1. SUBMITTER INFORMATION

a. Company Name:	USGI Medical
b. Company Address:	1140 Calle Cordillera San Clemente, CA 92673
c. Telephone: Fax:	(949) 369-3890 (949) 369-3891
d. Contact Person:	Mary Lou Mooney Vice President of Clinical, Regulatory & Quality
e. Date Summary Prepared:	January 14, 2011

2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	g-Prox EZ Endoscopic Grasper
b. Common Name:	Grasper
c. Classification Name:	Endoscope and accessories, 21 CFR 876.1500

3. IDENTIFICATION OF PREDICATE DEVICES

g-Prox Endoscopic Grasper	USGI Medical (K093018)

4. DESCRIPTION OF THE DEVICE

The g-Prox EZ Endoscopic Grasper is a sterile, single patient use device used for tissue grasping and mobilization. It is available in two jaw lengths. It includes a lumen that can accept the g-Cath Tissue Anchor Delivery Catheter and other small diameter instruments. It is comprised of a polycarbonate proximal handle, flexible shaft made of medical grade polymers and distal

stainless steel jaws. It has a nominal working length and outer diameter of 111 cm and 5.5 mm, respectively.

5. STATEMENT OF INTENDED USE

The g-Prox EZ Endoscopic Grasper is intended for use in minimally invasive procedures to facilitate tissue grasping and mobilization.

6. COMPARISON WITH PREDICATE DEVICES

The g-Prox EZ Endoscopic Grasper is comparable to the predicate device in terms of intended use, technology, and materials. The shaft and distal jaw materials are identical to those used in the predicate device and are provided in the same sizes. The g-Prox EZ device handle is made of polycarbonate instead of Delrin. Both the g-Prox EZ and the predicate device have the identical intended use and principals of operation. Both the g-Prox EZ and the predicate device include a lumen that can accept the g-Cath Tissue Anchor Delivery Catheter and other small diameter instruments. The g-Prox EZ includes a suture cutting component in the jaw to allow the user to cut the g-Cath anchor suture tail with the g-Prox EZ.

7. SUMMARY OF PERFORMANCE DATA

Design control activities for the described modifications were completed in accordance with 21CFR 820.30 and USGI Medical documented design control procedures. Human factors considerations were also incorporated into the device modifications. Risk analysis was performed in accordance with USGI Medical procedures to identify any risks associated with the modifications.

Non-clinical performance testing was conducted to ensure that the device performs as intended when used in accordance with its instructions for use and to demonstrate equivalence to the predicate device. Testing focused on those performance features related to the modifications and included device integrity testing (i.e., bond joint strength), functionality and in vivo simulated use testing. Test data confirmed that the modified g-Prox EZ device demonstrated equivalent safety and performance to the predicate device.

In conclusion, non-clinical performance data demonstrate that the g-Prox EZ Endoscopic Grasper is as safe, effective and performs as well as the g-Prox predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

USGI Medical
% Ms. Mary Lou Mooney
Vice President of Clinical,
Regulatory and Quality
1140 Calle Cordillera
San Clemente, California 92673

JAN 14 2011

Re: K103688
Trade/Device Name: g-Prox EZ Endoscopic Grasper
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCZ, HET
Dated: December 16, 2010
Received: December 17, 2010

Dear Ms. Mooney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103688

Device Name: g-Prox Endoscopic Grasper

Indications For Use
510(k) Number (if known):

The USGI g-Prox EZ Endoscopic Grasper is intended for use in minimally Invasive procedures to facilitate tissue grasping and manipulation.

Prescription Use __√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103688